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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,795	05/28/2004	Michael A. Slivka	101896-252 (DEP5319)	3794
21125 7590 06/19/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/709,795	Applicant(s) SLIVKA ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-27, 29-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 13-16 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-12, 17-19, 21-24, 26, 27, 29-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>DE4107480A1</u> |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 4th, 2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 9-12, 17, 19, 21, 22, 24, 26, 29-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich et al (DE 41 07 480 A1).

Ulrich et al disclose (**Figure 9**) a device comprising: a bone-engaging member (**1**) having a head formed thereon; a U-shaped receiver member (**2 and 5 together**); the receiver (**2 and 5**) having a proximal seat (**30**) that receives a spinal rod (which is either rigid or flexible since any material can be deemed one of the two); a threaded

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setscrew/fastener (12) to mate with the receiver to lock the spinal rod in position while allowing free movement of the bone-engaging member (1); the bone-engaging member (1) has its head mated to a distal portion (2) of the receiver in an optional polyaxial connection (**Column 3, Line 55 through Column 4, Line 1** stating a ball joint is known in place of the simple swivel joint depicted).

Claims 1, 6-12, 17-19, 21, 22, 24, 26, 27, 29-33 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Parker (US Patent Application Publication 2004/0260284).

Parker discloses (**Figure 1**) a device comprising: a bone-engaging member (105) having a spherical head (110) formed thereon; a U-shaped receiver member (115); the receiver (115) having a proximal seat (155) that receives a (rigid or flexible since it has to be one) spinal rod (200); a threaded (150) setscrew/fastener (145) to mate with the receiver to lock the spinal rod in position while allowing free polyaxial movement of the bone-engaging member (105); the bone-engaging member (105) has its head mated to a distal portion (112) of the receiver.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 18, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al.

Ulrich et al disclose all of the claimed limitations except for the bone-engaging member having a spherical head as well as the spinal fixation element formed from a material from the group consisting of stainless steel, titanium, non-absorbable polymers, absorbable polymers, and combinations thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form a spherical head on the bone-engaging member since Ulrich et al already disclosed that a ball joint is a known connection between element (2) and the bone-engaging member (1) leaving the choice merely to which component (2) or (1) receiving the socket and the other the ball. Further should applicant assert that one would have provided the ball on element (2) instead of (1), such would not obviate the problem since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

It would have also been obvious to one having ordinary skill in the art at the time the invention was made to select a material from applicant's group of appropriate materials since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parker. Parker discloses all of the claimed limitations except for the spinal fixation element being formed from a material from the group consisting of stainless steel, titanium, non-absorbable polymers, absorbable polymers, and combinations thereof.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a material from applicant's group of appropriate materials since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
June 13th, 2007



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER